ONTARIO EXPORTS INC.
OPENING DOORS WORLDWIDE

56 Wellesley Street West
7th Floor
Toronto, Ontario M7A 2E4
Tel: 416 325-6658
Fax: 416 325-6509
E-Mail: debbie.walker@edt.gov.on.ca

October 8, 1999

Dockets Management Branch
(HFA 305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland, U.S.A.
20852

Fax: 301-443-6906

RE: **Federal Register Vol 64, No 93, May 14, 1999**
Foreign Establishment Registration and Listing

Docket Number 98N –1215

Dear Sir or Madam,

Ontario Exports Inc. is the lead trade agency for the Government of Ontario. As such, its mandate is to increase Ontario's share of the global export market by expanding the number of small and medium-sized businesses exporting. The benefits to Ontario are substantial, not only in terms of increased employment and the resulting tax revenues it generates, but also in terms of Ontario's overall economic growth.

As the Area Director, US Healthcare, I have received substantial mail and numerous telephone calls from many of my clients – primarily small and medium sized enterprises. All have expressed concern over the proposed FDA Foreign Establishment and Listing amendment. It should be noted that a number of Ontario firms export their medical products to the United States.

The overwhelming response from Ontario manufacturers has been as follows:

1. **Device Listing** – This is not seen to be a significant issue primarily due to the fact that much of this is already captured in the Pre-Market Approval process.

2. **Foreign Establishment Registration** – This too is not considered an onerous requirement for foreign firms to register with the US FDA. Many countries require a similar registration, including Health Canada.

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3. **Designated Agent** – Overwhelming, this proposal was seen to be an unreasonable barrier to trade between Canada and the United States. In this age of globalization, the proximity of Canada to the United States and the reciprocal relationship between the regulatory agencies make the requirement for a US agent both unnecessary, costly and counterproductive. There exists already an excellent communication track record between the FDA and Canadian manufacturers. The implementation of a US agent is viewed as having no value add, rather, it is perceived that the introduction of a third party could, in fact, lead to delays and misinformation.

Given the litigious nature of the US healthcare market, the financial burden for small manufacturers to hire an agent is considerable. It can safely be assumed that any agent acting on behalf of a company would likely charge a substantial fee for service. It is also doubtful that firms would want to designate their existing distributors for this task, given confidentiality issues. And customs brokers and other types of service oriented firms would also be loath to take on this responsibility.

It should be noted that Canada currently has no reciprocal requirement for a designated agent. This creates an unfair and uneven playing field as it relates to Canadian companies competing equally with US manufacturers – whether in Canada or in the United States. I can assure you that should the US designated agent requirement be implemented, the Canadian government will be hard pressed not to enact similar requirements as a result of the heavy lobbying that industry associations and their members will organize. I am sure that US trade associations would be quite reluctant to see similar burdens placed upon their members.

In closing, I strongly believe that this proposal is contrary to the philosophy and intent of NAFTA. There exists already an effective channel of communication between Canadian manufacturers and the FDA. There is no benefit that I am aware of to enforce the establishment of a US designated agent. I hope that you will reconsider its implementation as it relates to Canadian manufacturers.

I trust that these comments will be viewed seriously and await your decision.

Sincerely,

Debbie Walker
Area Director
US Healthcare

Cc Ms Birgit Mattiesen, Canadian Embassy, Washington
Mr. Christian Dube, AOMM